UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,647	03/10/2000	Andrew D. Murdin	032931/0227	5021

7590 09/01/2004

Bernhard D Saxe
Foley & Lardner
3000 K Street NW
Suite 500
Washington, DC 20007-5109

EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	**Application No.** 09/523,647	**Applicant(s)** MURDIN ET AL.	
	Examiner Mark Navarro	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 July 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ they raise the issue of new matter (see Note below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See attached*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *8-9, 11, 40-42, 48-52*.

   Claim(s) withdrawn from consideration: _____.
8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ADVISORY ACTION

Applicants amendment filed July 19, 2004 has been received and entered. Accordingly, claims 8-9, 11, 40-42, 44-46, and 48-52 remain pending in the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The rejection of claims 8-9, 11, 40-42, 44-46, and 48-52 under 35 U.S.C. 103(a) as being unpatentable over Watson et al in view of Denney Jr., and Scaria et al is maintained.

Applicants are asserting that none of the cited references suggest using a nucleic acid molecule encoding SEQ ID NO: 2 operably linked to a promoter functional in a mammalian cell, as a vaccine. Applicants further assert that only a few of the 1296 coding sequences of C. pneumoniae are useful as vaccines. Applicants finally assert that there is no motivation to link a nucleic acid molecule encoding SEQ ID NO: 2 to a promoter functional in a mammalian cell because a skilled person cannot reasonably expect that such a combination would lead to a useful vaccine.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that none of the cited references suggest using a nucleic acid molecule encoding SEQ ID NO: 2 operably linked to a promoter functional in a mammalian cell, as a vaccine, and that only a few of the 1296 coding sequences of C. pneumoniae are useful as vaccines. However, a claimed compound may be obvious because it was suggested by, or structurally similar to, a prior art compound even though a particular benefit of the claimed compound asserted by patentee is not expressly disclosed in the prior art. It is the differences in fact in their respective properties which are determinative of nonobviousness. If the prior art compound does in fact possess a particular benefit, even though the benefit is not recognized in the prior art, Applicant's recognition of the benefit is not in itself sufficient to distinguish the claimed compound from the prior art. In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1991).

Finally, Applicants have assumed that the only possible reason for expressing the protein is for the same reasons that they have done, i.e., a vaccine. However, the art clearly teaches that the nucleotide sequence is that of a outer membrane protein of Chlamydia pneumoniae. As such, this is an obvious protein to use in a diagnostic test for detecting infection of a Chlamydia pathogen. Accordingly, one of ordinary skill in the art would be motivated to produce large quantities of the protein.

The claims are drawn to a vaccine vector comprising an isolated nucleic acid molecule which encodes SEQ ID NO: 2, wherein the nucleic acid molecule is operably linked to a promoter functional in a mammalian cell.

Watson et al (Nucleic Acids Research Vol. 18, No. 17, page 5299, 1990) teach of the nucleotide sequence of the 60 kDa cysteine rich outer membrane protein of Chlamydia pneumoniae. The DNA sequence and encoded protein disclosed by Watson et al are identical to SEQ ID NO: 1-2 of the instant invention.

Watson et al do not teach of the nucleic acid molecule operably linked to a promoter functional in a mammalian cell.

Denney Jr. (US Patent Number 5,776,746) teach that the human cytomegalovirus (CMV) major immediate early gene enhancer/promoter is active in a broad range of cell types. Denney Jr. further teach that vectors containing the CMV enhancer/promoter increase the level of transcription of the desired antigen. (See column 16).

Scaria et al (US Patent Number 6,020,191) teach that vectors comprising a CMV promoter are advantageous in that they provide longer duration of expression of a transgene. (See column 4).

Given that 1) Watson et al has disclosed of the exact nucleotide sequence and exact encoded protein sequence as instantly claimed, and that 2) Denney Jr. has taught that the CMV promoter increases the level of transcription of a desired antigen, and that 3) Scaria et al has taught that CMV promoters are advantageous in that they provide longer duration of expression of a transgene, it would have been prima facie obvious to

have taken the DNA molecule disclosed by Watson et al and to have fused it in frame to a CMV promoter. One of skill in the art would have been motivated to create this combination based on the teachings of Denney Jr. and Scaria et al that CMV promoters increase the level of transcription of a desired antigen and provide longer duration of expression of a transgene.

For reasons of record, as well as the reasons set forth above this rejection is maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (703) 306-3225. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Mark Navarro
Primary Examiner
August 26, 2004